

REMARKS

Upon entry of the present reply, claims 1-16 and 20-31 will remain pending.

Reconsideration of the rejections and allowance of the application in view of the following remarks are respectfully requested.

Request for Withdrawal of Finality of Office Action

As discussed with the Examiners during the above-noted interview, the rejections of record are improper and without appropriate basis, because they rely upon five U.S. patents, i.e., U.S. Patent Nos. 2,876,167, 6,331,291, 6,174,516, 5,851,167 and 6,294,155; however, the U.S. patents are not included in the statement of the rejections.

In particular, at page 3 of the Office Action, it is asserted that:

Applicant argues superior whitening purposes of calcium pyrophosphate as compared to the commonly used calcium carbonate. However, calcium pyrophosphate is commonly used in prior art dentifrices (See for example, US Patent No 2,876,167, US Patent No 6,331,291, US Patent No 6,174,516, and US Patent No 5,851,514.) In fact the stain removal or "whitening" ability calcium pyrophosphate is used as a standard by which dentifrices are measured for their stain removal or whitening capability. For example, Thomas et al , (US 6,294,155) states that calcium pyrophosphate is a reference material of the American Dental Association and that the stain reduction resulting from calcium pyrophosphate use is taken to be by definition 100 (see col. 6, lines 32-51.0) Because calcium pyrophosphate is commonly used and unambiguously disclosed in Rajaiah the artisan would have chosen it to be used in the composition of Rajaiah. Because the artisan would not have necessarily preferred calcium carbonate over calcium pyrophosphate, Applicant's data is not persuasive. Furthermore, the artisan would expect some differences between calcium carbonate and calcium pyrophosphate since they are different compounds.

As discussed with the Examiner, the rejections are relying upon disclosures of these patents in an attempt to establish a *prima facie* case of obviousness. However, the rejections do

not indicate that these patents are part of the rejections nor do the rejections state how the patents are being combined with Rajaiah.

Accordingly, the rejections are not clearly set forth in the Final Office Action and rely upon documentary support that is not included in the rejections. Therefore, the finality of the Office Action is improper. Therefore, withdrawal of the finality of the Office Action is respectfully requested.

Statement of Interview

Applicant expresses appreciation for the courtesies extended by Examiner Fetteroff and Examiner Webb to Applicant's representative Arnold Turk during a January 27, 2007 telephone interview.

During the interview, the Office Action including the rejections of record and Applicant's claimed subject matter were discussed. Applicant's representative noted that the rejections do not have an appropriate basis because the Office Action improperly references five patents on page 3 to support the rejections without including these patents in the rejections. Applicant's representative presented arguments that the rejections were not clearly set forth and the finality should therefore be withdrawn.

Applicant's representative also submitted that the rejections do not appear to provide sufficient basis for arguing that the product of Rajaiah et al. includes the weigh percent of sold materials as recited in Applicant's claims. The Examiners indicated that the claimed subject matter was met as long as the prior art included solids to which Applicant's representative

submitted that the rejections must establish that the prior art includes each and every feature recited in Applicant's claims including the recited weight percent of solid materials.

Additionally, arguments were submitted relating to the broad disclosure of Rajaiah et al. including a lack of direction for choosing Applicant's recited calcium pyrophosphate. Moreover, the unexpected showings set forth in Applicant's originally filed application including a comparison between calcium carbonate and Applicant's recited calcium pyrophosphate were discussed.

The Examiners did not make any commitment, and indicated that they will consider arguments upon the submission of a written response.

Information Disclosure Statement

Applicant expresses appreciation for the Examiner's confirmation of consideration of Applicant's Information Disclosure Statements, filed June 25, 2008, by including an initialed copy of the Form PTO-1449 with the Office Action.

Applicant is submitting on even date herewith a Second Supplemental Information Disclosure Statement. The Examiner is requested to consider the Second Supplemental Information Disclosure Statement and to confirm such consideration by including an initialed copy of the Form PTO-1449 submitted therewith with the next communication from the Patent and Trademark Office.

Applicant submits that certification is not needed for consideration the Second Supplemental Information Disclosure Statement because the finality of the Office Action is improper and should be withdrawn.

If any fee is needed for consideration of the Second Supplemental Information Disclosure Statement, including any fee under 37 C.F.R. 1.17(p), this is express authorization to charge any required fee to Deposit Account No. 19-0089.

Response to Art Based Rejections

The following art based rejections are set forth in the Office Action.

- (a) Claims 1-11, 13-16 and 20-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rajaiah et al, US 2003/0072841.
- (b) Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rajaiah et al, US 2003/0072841, in view of Gibbs et al., International Journal of Food Sciences and Nutrition 1999.

Applicant once again submits that the rejections based upon Rajaiah, either alone or in view of Gibbs, are without appropriate basis, and should be withdrawn at least for the reasons set forth below.

Initially, Applicant submits that the basis of the rejections is not clear because, as discussed above, the Final Office Action includes discussion of five U.S. patents in support of the rejection without formally including these patents in the rejection. Accordingly, for at least this reason, the rejections of record should be withdrawn or the rejections clarified in a non-final Office Action.

Applicant's independent claim 1 is directed to a solid, oral tooth whitening composition comprising more than 75% by weight of solid materials, said composition comprising:

- (a) a chewing gum or confectionary base;
- (b) chewing gum or confectionary additives; and

(c) a tooth whitening agent comprising calcium pyrophosphate present in an amount of between 0.5% and 9% by weight of the composition, excluding any coating compositions.

As recognized in the rejections, Rajaiah does not teach such a composition. Instead, the rejections contended in the previous Office Action that, despite the fact that one must “pick and choose” from different lists of components throughout the reference, that it would have been obvious in a self-evident manner to have selected, for the chewing gum/confectionary composition of Rajaiah, calcium pyrophosphate as well as sugar-free sweeteners, flavors, urea, vitamin C, and sodium bicarbonate, motivated by the unambiguous disclosure of each individually, and consistent with the basic principle of patent prosecution that a reference should be considered as expansively as is reasonable in determining the full scope of the contents within its four corners. Moreover, the rejections asserted that the adjustment of particular conventional working conditions of the composition of Rajaiah is deemed a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Applicant submits that the rejections are without sufficient basis, because the rejections do not indicate how Rajaiah is being modified, but merely make ambiguous assertions. For example, the rejections contended that the claimed subject matter is “obvious in a self-evident manner” in view of some asserted “basis principle of patent prosecution”. However, the rejections did not indicate why one having ordinary skill in the art would have picked and chosen components disclosed in Rajaiah to arrive at Applicant’s recited subject matter. This is especially the situation when there is no indication in the rejections what routine optimization would have been performed and/or why one having ordinary skill in the art would have manipulated the composition disclosed by Rajaiah to arrive at the claimed subject matter. This deficiency of the rejections has not been addressed in the Final Office Action.

As discussed during the above-noted interview and in Applicant's previous response, Rajaiah discloses chewing gum formulations comprising two components; a polybutene component and a chewing gum component [0009]. The polybutene component may comprise 50-90% of the composition [0024], the remainder being the "chewing gum component". The polybutene component of the composition according to Rajaiah is a flowable liquid [0026], and thus not a "solid component". Thus, in order for the skilled person to arrive at the claimed subject matter starting from Rajaiah, in addition to "picking and choosing" the most suitable abrasive in the most preferred range, would also need to change the polybutene component of Rajaiah, which is an essential part of the composition disclosed by Rajaiah. Thus, to arrive at Applicant's claimed subject matter would require that the desired composition of Rajaiah including the polybutene component be essentially destroyed to arrive at the claimed subject matter. The rejections have not established any motivation and/or any reason why one having ordinary skill in the art would, in effect, attempt to modify an what should be considered to be an essential component of the composition of Rajaiah to arrive at Applicant's claimed subject matter. While Applicant's claims do not exclude the presence of polybutene, one having ordinary skill in the art would not have modified Rajaiah to arrive at the composition recited in Applicant's independent claim 1, and further defined in the dependent claims.

In the Final Office Action, the Examiner contends that, Applicant's invention is not drawn to a method of making a chewing gum or confectionary, but a product comprising more than 75% by weight of solid materials. The product of Rajaiah is solid insofar as it is in the form of a chewing gum. The product, including polybutene, therefore comprise solid materials". **As discussed the Examiner during the above-noted interview, the rejections must establish that a the prior art teaches or suggests, amongst the other features recited in Applicant's**

claims, a solid, oral tooth whitening composition comprising more than 75% by weight of solid materials. A mere assertion of “comprising solid materials” in the Final Office Action does not arrive at the claimed subject matter including more than 75% by weight of solid materials.

Further expanding upon the deficiencies of Rajaiah, Rajaiah discloses in [0059] typical abrasive polishing materials as including “silica gels and precipitates; aluminas; water insoluble phosphates (including orthophosphates, polymetaphosphates, and pyrophosphates); and mixtures thereof”. In [0059], Rajaiah further discloses specific examples of abrasives as including dicalcium orthophosphate dihydrate, calcium pyrophosphate, tricalcium phosphate, calcium polymetaphosphate, insoluble sodium polymetaphosphate, hydrated alumina, beta calcium pyrophosphate, calcium carbonate, and resinous abrasive materials such as particulate condensation products of urea and formaldehyde and melamine urea formaldehyde. Mixtures of abrasives may also be used.

In [0059], Rajaiah further discloses that: “The abrasive in the chewing gum compositions is generally from about 1% to about 70%, in one embodiment from about 5% to about 50%, by weight of the chewing gum or confection component.”

Rajaiah does not disclose a whitening effect of the abrasive and Rajaiah does not contain any teaching or suggestion as to the particular selection of calcium pyrophosphate among several other abrasives for any purpose, let alone as an abrasive having a superior whitening effect. Further, Rajaiah does not contain any teaching or suggestion as to the particular selection of the preferred range of 0.5% - 9% calcium pyrophosphate on the basis of a proposed usable range of abrasive of 1-70%, an embodiment from about 5% to about 50%, of the solid oral compositions.

Rajaiah does not disclose the whitening effect of the abrasive. Consequently, there is no teaching or suggestion to arrive at Applicant's claimed subject matter in Rajaiah .

Rajaiah does not disclose the specific features of the present invention and therefore does not disclose the solution of the present invention.

The rejections of record to do point to any disclosure of Rajaiah, or any other document, that would lead one having ordinary skill in the art to arrive at the recited tooth whitening agent comprising calcium pyrophosphate in an amount of 0.5% - 9 % as recited in Applicant's independent claim 1. Rajaiah merely discloses the possibility of adding to a chewing gum calcium pyrophosphate as one abrasive among a myriad of other possible abrasives, with the abrasives being proposed to be applied in a range of 1-70% of the solid oral compositions.

Applicant further notes that calcium pyrophosphate, according to Rajaiah is placed as one among several abrasives [0059], though Rajaiah additionally teaches the possibility of adding whitening substances [0039] to solid oral compositions.

Calcium pyrophosphate is not mentioned among the preferred whitening agents mentioned in [0039] in Rajaiah. There is no teaching or suggestion in Rajaiah as to any particular suitability of calcium pyrophosphate as a whitening agent, and especially there is no teaching or suggestion in Rajaiah to the particular suitability of calcium pyrophosphate over other abrasives as a whitening agent.

Still further, while Rajaiah also discusses the use of pyrophosphates as potential anti-calculus agents in paragraph [0032], Rajaiah does not list calcium pyrophosphate as a possible candidate. Not notwithstanding this, the paragraph states the anti-calculus agent may be present from about 0.001% to about 50%, by weight of the polybutene component (the polybutene component could be present in the composition between about 1% to 99.9%) and all of the

examples clearly teach using much higher levels of anti-calculus agents (13, 15 and 25%) in the composition. Therefore, Rajaiah specifically teaches the skilled reader towards using a higher percentage of a pyrophosphate in a tooth whitening composition, rather than the range recited by Applicant.

Moreover, the Examiner's attention is directed to the experiments disclosed in Applicant's specification. Prior art compositions comprising different concentrations of calcium pyrophosphate and calcium carbonate, respectively, have been tested, showing the superiority of a particular abrasive in a particular range for a particular purpose. Accordingly, the present application contains experimental data showing that calcium pyrophosphate is superior for whitening purposes to the commonly used calcium carbonate when formulated in chewing gum compositions (see e.g. table 1, page 16), and that calcium pyrophosphate is superior in inhibiting further discoloration of teeth (see e.g. table 2, page 18).

The experimental data in the originally filed application clearly shows that a lower amount of calcium pyrophosphate (4.5 to 6.5%) advantageously provides an improved tooth whitening effect, when compared to prior art tooth whitening agent calcium carbonate

The Final Office Action merely indicates that the showings are not persuasive, but improperly does not provide any explanation as to what is considered any deficiency in the showings in the originally filed application. Accordingly, the Examiner is requested to provide a complete response to Applicant's arguments relating to the unexpected showings in the originally filed application.

Regarding the five U.S. patents mentioned in the Final Office Action, Applicant notes that the application of these patent to Applicant's claimed subject matter is not set forth in any rejection, and therefore response to a rejection using these patent is not required. Moreover, the

Final Office Action is not clear as to how these documents are being used in combination with Rajaiah. Therefore, Applicant awaits clarification as how the patents are being applied in a rejection prior to submitting arguments thereover in the event that the Examiner deems that the patents support a rejection of Applicant's claims. Applicant is not submitting that they have discovered calcium pyrophosphate, which may be disclosed in U.S. Patent Nos. 2,876,167, 6,331,291, 6,174,516, US 5,851,514 and US 6,294,155. Applicant is submitting that any combination of the prior art as set forth in the Office Action does not arrive at Applicant's claimed subject matter so that the rejections of record should be withdrawn.

Therefore, for at least the reasons set forth above, the composition recited in Applicant's independent claim 1 is not taught or suggest by Rajaiah.

Moreover, the dependent claims further patentably define the claimed subject matter, and are patentable for the features set forth the independent claim as well as for the features recited therein.

Thus, claim 2 further patentably recites that the calcium pyrophosphate is present in an amount of between 3% and 8% by weight of the composition, excluding any coating compositions.

Claim 3 further patentably recites that the gum base constitutes from 10% to 99% by weight of the composition.

Claim 4 further patentably recites that the gum base comprises at least one of the following; natural or synthetic elastomeric compounds, natural or synthetic resin compounds, fillers, softening compounds, antioxidants and colorants.

Claim 5 further patentably recites that the composition is formulated as a confectionary composition in which said confectionary base constitutes from 0% to 99% by weight of the

composition.

Claim 6 further patentably recites that the chewing gum or confectionary additives comprise at least one of the following ingredients: sweeteners, high intensity sweeteners, taste enhancers, flavoring agents, and coloring agents.

Claim 7 further patentably recites that the composition is essentially sugar-free.

Claim 8 further patentably recites that the composition comprises at least one additional tooth whitening agent.

Claim 9 further patentably recites that the at least one additional tooth whitening agent is present in between 0.01% and 10.0% by weight of the composition, excluding any coating.

Claim 10 further patentably recites that the at least one additional tooth whitening agent comprises a bicarbonate salt.

Claim 11 further patentably recites that the at least one additional tooth whitening agent comprises sodium bicarbonate, said agent being present in between 0.3% and 0.4% by weight of the composition, excluding any coating.

Claim 12 further patentably recites that the at least one of said additives and said tooth whitening agent is encapsulated.

Claim 13 further patentably recites that the composition further comprise at least one of the following: oral hygiene promoting agents, anti-calculus agents, anti-microbial agents, anti-inflammatory agents, desensitizing agents, therapeutically active agents, and remineralizing agents.

Claim 14 further patentably recites that the composition further comprises a supplement.

Claim 15 further patentably recites that the supplement comprises vitamin C.

Claim 16 further patentably recites that the oral hygiene promoting agent comprises urea,

said urea being present in between 0.15% and 25% by weight.

Claim 23 further patentably recites that the calcium pyrophosphate is present in an amount of between 4.5% and 7.5 % by weight of the composition, excluding any coating compositions.

Claim 24 further patentably recites that the calcium pyrophosphate is present in an amount of between 5.5% and 7 % by weight of the composition, excluding any coating compositions.

Claim 25 further patentably recites that the composition is formulated as a chewing gum composition wherein which said gum base constitutes from 15% to 80% by weight of the composition.

Claim 26 further patentably recites that the composition is formulated as a chewing gum composition wherein said gum base constitutes 25% to 60 % by weight of the composition.

Claim 27 further patentably recites that the at least one additional tooth whitening agent is present in between 0.1 and 2.0% by weight of the composition, excluding any coating.

Claim 28 further patentably recites that the at least one additional tooth whitening agent is present in between 0.25% and 1.0% by weight of the composition, excluding any coating.

Claim 29 further patentably recites that the oral hygiene promoting agent comprises urea, said urea being present in between 0.4% and 10% by weight.

Claim 30 further patentably recites that the oral hygiene promoting agent comprises urea, said urea being present in between 0.8% and 5% by weight.

Claim 31 further patentably recites the oral hygiene promoting agent comprises urea, said urea being present in between 1.5 % and 2.5% by weight.

Claim 20 patentably recites a method of whitening tooth surfaces by consuming a solid,

oral tooth whitening composition according to claim 1, which method is not taught or suggested in Rajaiah.

Claim 21 patentably recites a method of whitening tooth surfaces by consuming a solid, oral tooth whitening composition according to claim 1, said tooth surfaces being discolored after use of tobacco-related products, which method is not taught or suggested in Rajaiah.

Claim 22 patentably recites a method of whitening tooth surfaces by consuming a solid, oral tooth whitening composition according to claim 1, said tooth surfaces being discolored after use of coffee-related products, which method is not taught or suggested in Rajaiah.

Gibbs is utilized in the rejection of claim 12 solely for assertions that it would have been obvious to encapsulate to arrive at the subject matter recited in claim 12. However, whether or not encapsulation would have been obvious in view of Gibbs, for at least the reasons set forth above, Applicant's claimed subject matter would not be at hand.

Accordingly, the rejections of record should be withdrawn.

CONCLUSION

In view of the foregoing, the Examiner is respectfully requested to reconsider and withdraw the rejections of record, and allow each of the pending claims.

Applicants therefore respectfully request that an early indication of allowance of the application be indicated by the mailing of the Notices of Allowance and Allowability.

Should the Examiner have any questions regarding this application, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted
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